From the Society for Vascular Surgery

Role of aneurysm sac embolization during endovascular aneurysm repair in the prevention of type II endoleak-related complications

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Objective: **The goal of this study was to evaluate the role of intraoperative aneurysm sac embolization during endovascular aneurysm repair (EVAR) using a standard dose of coils and fibrin glue in the prevention of type II endoleak (EII).**
Methods: **Two groups were compared: 83 patients underwent standard EVAR during the period 2008-2009 (group A) and 79 patients underwent EVAR during the period 2010-2011 (group B). Computed tomography scans were evaluated with Osirix Pro 4.0 software to obtain aneurysm sac volume. EII rates at the first computed tomography scan follow-up, as well as midterm freedom from EII and freedom from related reintervention, were compared. Preoperative number of patent aortic side branches (inferior mesenteric artery, lumbar arteries, accessory renal arteries), sac thrombus, and sac volume were evaluated for their association with EII in the two groups using multiple logistic regressions.**
Results: **Patient characteristics, Society for Vascular Surgery comorbidity scores (0.85 ± 0.44 vs 0.82 ± 0.46; $P = .96$), and operative time (185 ± 52 vs 179 ± 49; $P = .92$) were similar for groups A and B. The first computed tomography scan (≤3 months) revealed a significantly larger number of EIIs in group A than in group B (23% vs 10%; $P = .02$). Spontaneous EII resolution occurred in 65% of patients in group A and in 79% in group B ($P = 1.0$), whereas sac volume increased in 25% and 10% ($P = .63$) of cases, respectively. At 18 months (range, 6 months to 4.4 years), overall mean differences in sac volume shrinkage (27 ± 12 cm^3 vs 25 ± 12 cm^3; $P = .19$) and freedom from EII (92% vs 96%; $P = .33$) were similar, whereas freedom from reintervention was significantly lower in group A (93% vs 99%; $P = .03$) than in group B. Multivariate analysis showed preoperative aneurysm sac volume >125 cm^3 to be the only independent significant predictor of EII (odds ratio, 4.0; 95% confidence interval, 1.5-10.5; $P = .005$).**
Conclusions: **Although further confirmatory studies are needed, sac embolization during EVAR may be a valid approach to preventing EII and its complications during short- and midterm follow-up. More aggressive intraoperative embolization should be considered for patients with a preoperative aneurysm sac volume >125 cm^3. (J Vasc Surg 2013;57:934-41.)**

Type II endoleak (EII) occurs in about 10% to 30% of patients after endovascular aneurysm repair (EVAR), because of retrograde flow from aortic side-branch vessels into the abdominal aortic aneurysm (AAA) sac.[1,2] Most types of EII are innocuous and resolve spontaneously after a variable period, but those with a persistent mechanism of inflow-outflow between patent branches and the sac could cause significant aneurysm sac enlargement or be persistent; these cases have been reported to have a higher risk of adverse outcomes.[3,4] Secondary interventions such as transarterial embolization and endoscopic ligation of the feeding branches, direct sac puncture, and aneurysm sac plication are reported in about 10% of cases[5,6]; the need for surgical reconstruction with endograft explantation is rare.

The additional medical expenses incurred for these additional procedures, as well as the increased exposure of patients to radiation and contrast agents during follow-up, represent a limitation to EVAR and occasionally can lead to a waste of its advantages in terms of costs and clinical success.

In this scenario, prevention of EII formation could be a valid strategy limiting this complication; previous reports have indicated that injection of fibrin glue alone or in association with microcoils into the aneurysmal sac during EVAR can facilitate sac thrombosis and reduce the incidence of EII.[7,8] However, the exact dose of material needed to effectively prevent this complication has not yet been standardized, and no reliable preoperative predictive parameters are currently available.

The purpose of this study was to review our experience in the treatment of AAAs by aneurysm sac embolization during EVAR (embo-EVAR) using a standard dose of fibrin glue and coils and to compare the results with those

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of traditional EVAR with respect to safety and efficacy. Furthermore, we investigated whether aneurysm sac volumetric analysis and other anatomical characteristics identified on the preoperative computed tomography (CT) scan could be reliable predictors of the efficacy of embo-EVAR in the prevention of EII.

METHODS

Patients. A retrospective review was performed of all consecutive patients admitted to the Clinic of Vascular and Endovascular Surgery of Padova University who underwent EVAR for infrarenal AAAs according to the device's instructions for use between 2008 and 2011. From January 2008 to December 2009, 83 patients underwent standard EVAR (group A), and from January 2010 to October 2011, all patients (n = 79) eligible for EVAR underwent contemporary aneurysm sac embolization with a standard dose of coils and fibrin glue (group B). Informed consent requirements were waived for this study, which was approved by the Institutional Clinical Ethics Committee. Demographics, preoperative characteristics, perioperative outcomes, and follow-up data were obtained through review of patients' medical records, pre- and postoperative CT angiograms, and invasive diagnostic studies.

Inclusion and exclusion criteria. In both groups A and B, only patients anatomically suitable for EVAR with infrarenal AAAs were included. All EVAR patients who underwent associated complex procedures such as chimney grafts and branched and fenestrated grafts were excluded. All commercially available aortobifurcated endografts were included in this study, whereas aortouniliac and tubular grafts and the double-barrel technique were not included. Urgent or emergent EVAR procedures were excluded from this study.

Treatment and definitions. Since January 2010 at our institution, to prevent EII, EVAR has been performed in association with aneurysm sac embolization. Our protocol, which applied only to group B, is based on injection of a "standard" dose of material. The required dose of fibrin sealant to fix a 16-cm^2 surface is about 5 mL. However, its use as an injectable matrix for aneurysm sac embolization represents an off-label application. Previous reports describe variable doses of both fibrin glue (from 5 to ≥10 mL) and platinum coils (from 1 to ≥3) based on aneurysm maximum diameter or persistence of an EII at the final intraoperative angiogram.[7,8] On the basis of this previous experience, we planned to use 5 mL fibrin glue (Tissucol; Baxter Hyland Immuno AG, Vienna, Austria) and three coils (MReye Embolization Coil, IMWCE-35-10-20; Cook Medical, Limerick, Ireland) during EVAR independent of preoperative aneurysm dimensions and anatomical characteristics. Our choice to use MReye coils, instead of the formerly used platinum coils, was based on the potential for minor scatter artifacts in the CT angiogram in the immediate vicinity of the coil and guaranteed better detection of eventual endoleak during follow-up (Fig 1, *A* and *B*).

Operative comorbidity risk was evaluated using the Society for Vascular Surgery comorbidity grading system[9] and the American Society of Anesthesiologists score. Early outcomes (≤30 days from surgery) were evaluated using comparisons of periprocedural data and associated morbidity and mortality between the two groups. In accordance with the current standard report for EVAR,[10] primary clinical success is defined as absence of aneurysm-related death, aneurysm rupture, conversion to open surgery, and secondary endovascular or surgical procedures.

For all patients in both groups, aneurysm sac maximum diameter and volume were calculated pre- and postsurgery. Aneurysm sac volume was calculated on 1-mm-thin slices of CT angiograms using Osirix Pro 4.0 software. One trained medical doctor manually tracked regions of interest of the aneurysm external wall every 8 mm from axial cuts. Subsequently, the software was asked to generate missing regions of interest and compute aneurysm sac volume intended in cubic centimeters (Fig 2, *A* and *B*). To identify all minimal modifications of aneurysm volume between the pre- and postoperative CT angiograms and to ensure homogeneous measurement, the calculation was performed, by definition, only for the infrarenal abdominal aorta starting below the lowest renal artery and ending at the aortic bifurcation. For three-dimensional volume change, 5% or more was considered significant on the basis of Society for Vascular Surgery reporting standards.[9,10]

Preoperative CT angiogram anatomic factors including patency of the inferior mesenteric artery (IMA) or paired lumbar arteries and presence of accessory renal arteries were also evaluated. Furthermore, quantity of sac thrombus was evaluated and classified according to the percentage of aneurysm sac volume (0%-25%, 26%-50%, 51%-75%). All these parameters were evaluated separately and combined in the multivariate analysis to determine any association with EII.

The same two operators who have much experience in EVAR performed the procedure for both groups routinely.

Follow-up was performed in all patients in both groups by obtaining contrast CT angiograms at approximately 3, 6, and 12 months and yearly after that. Average length of follow-up was 2 years 5 months (range, 6 months to 4 years 4 months), with mean follow-up periods of 3½ years for group A (3.1 ± 1.4) and 1½ years for group B (1.1 ± 0.7).

The definition "freedom from reintervention" was applied to those patients who, during their follow-up, did not have an EII or had an EII that did not require additional procedures. Indications for reintervention related to the presence of an EII were >5-mm increase in maximum diameter of the aneurysm sac diameter within two consecutive CT angiograms on follow-up and persistent EII (EII on three or more consecutive CT angiograms during follow-up) with any increase in aneurysm sac diameter.

Operative technique. This technique was intended for group B only. Endoluminal access to the aorta was gained through a center puncture with an 18-gauge needle in both common femoral arteries and placement of a 10F sheath over the wire. A second unilateral puncture in

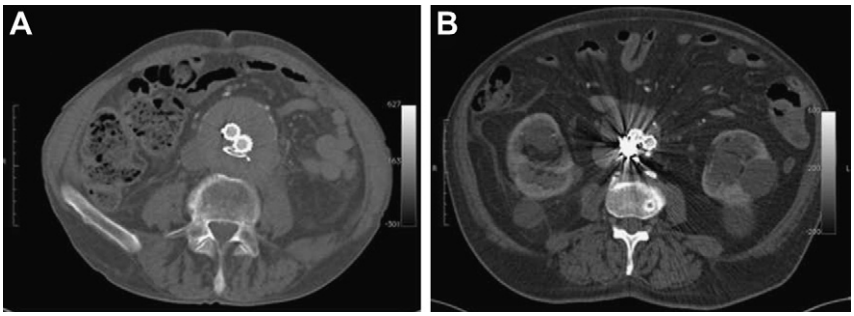

Fig 1. Axial computed tomography (CT) angiogram images of aortic aneurysm sacs after endovascular aneurysm repair (EVAR) with aneurysm sac embolization using **(A)** Tornado MReye coils and **(B)** platinum coils.

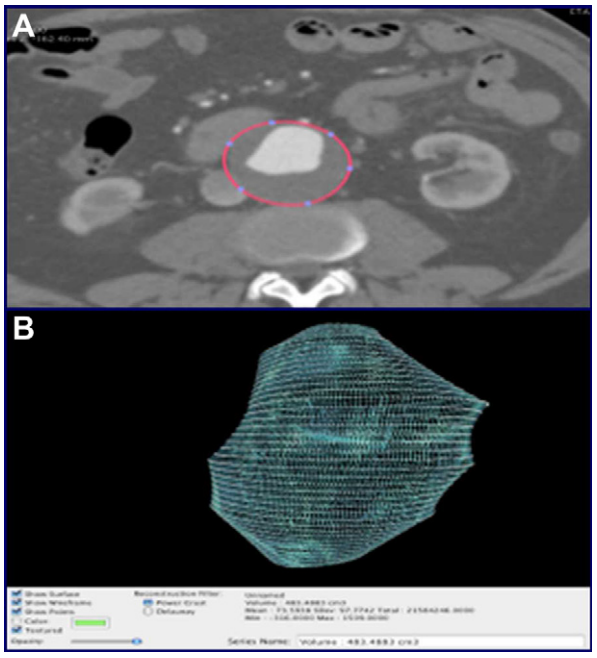

Fig 2. A preoperative analysis of aneurysm sac volume with Osirix Pro 4.0 software. **A,** After selection of regions of interest of the external aortic wall at axial cuts. **B,** Volume rendering with values obtained in cubic centimeters.

the side of the contralateral limb was made just below the 10F sheath, and a standard J 0.035-inch guidewire advanced under fluoroscopy to the AAA sac. Subsequently, a 23-cm-long 5F Brite Tip introducer was advanced over the wire. At this point, a standard EVAR was performed over the wires placed through the bilateral femoral artery access.

Once the endograft was completely deployed and the aneurysm excluded, three Tornado coils, 35, 10, and 20 mm (Cook Medical, Bloomington, Ind), were advanced into the sac through a 5F catheter via the 5F introducer. Subsequently, the catheter was replaced with a 35-cm-long Duplocath catheter (Baxter International, Deerfield, Ill) connected to a Duployect syringe clip; this was fed into the introducer until it reached the aneurysm sac. At this point, to prevent distal embolization of the fibrin glue, two noncompliant balloons were inflated on both iliac graft branches, and a total of 5 mL of glue was injected into the aneurysm sac through the two-way catheter. After approximately 40 seconds, the balloons were deflated, the Duplocath catheter was removed, and the final angiogram was obtained to verify sac thrombosis and document eventual residual endoleak.

Intraoperative and postoperative therapy was the same for both groups; in particular, the dose of anticoagulant during the procedure was 5000 USP heparin units given by endovenous infusion. From the first postprocedural day, patients were maintained on single antiplatelet therapy.

Statistical analysis. Means and standard deviations of aneurysm sac volume before and after surgery were compared between the two procedures by two-sample *t*-test. Pearson, χ^2, and Fisher exact tests were used for analysis of categorical variables. Kaplan-Meier freedom from reintervention was estimated, and the log-rank *P* value was used to compare the two procedures. The multiple logistic regression model was used to identify independent predictors of EII. $P < .05$ was used to determine statistical significance.

RESULTS

Age was similar for patients in group A (70.7 ± 7.2 years) and group B (71.2 ± 6.1 years; $P = .95$), as were the proportions of patients aged <60 years at the time of surgery ($P = 1.0$). The majority of patients in both groups were male (88% and 91%, respectively; $P = .43$) and the two groups were also similar in terms of cardiovascular risk factors (Table I), anesthesiology (American Society of Anesthesiologists score; $P = .75$), and perioperative risk assessment (Society for Vascular Surgery sum score; $P = .96$).

Mean preoperative aneurysm diameter was similar for the two groups (5.7 ± 1.1 cm vs 5.8 ± 0.9; $P = .94$), as was aneurysm volume (144 ± 97 vs 128 ± 68; $P = .89$). Of the anatomical preoperative characteristics identified on the preoperative CT angiogram, only the proportion of patent IMA was significantly higher in group B than in group A (83% vs 70%; $P = .04$); no differences were

Table I. Demographics, cardiovascular risk factors, and perioperative risk assessment in the 162 patients who underwent standard EVAR (group A) and EVAR with aneurysm sac embolization (group B)

	Group A (n = 83)[a]	*Group B (n = 79)*[a]	P *value*
Demographics			
Age, years	70.7 ± 7.2	71.2 ± 6.1	.95
Age <60 years	3 (4)	2 (3)	1.0
Male gender	73 (88)	72 (91)	.43
Cardiovascular risk factors			
BMI, kg/m^2	27.6 ± 4.5	28.1 ± 5.0	.94
Hypertension	66 (79)	64 (81)	.85
Diabetes	8 (10)	9 (11)	.80
Smoking[b]	42 (51)	49 (62)	.15
Coronary artery disease	41 (49)	46 (58)	.03[c]
History of CABG /PTCA	21 (25)	24 (30)	.48
Chronic heart failure	3 (4)	2 (3)	1.0
Ejection fraction <45%	7 (8)	11 (14)	.32
CRI (Cr > 1.5 mg/dL)	18 (22)	18 (23)	.5
Dialysis	1 (1)	1 (1)	.49
COPD	15 (18)	18 (23)	.55
Home oxygen therapy	2 (2)	3 (4)	.67
Perioperative risk assessment			
ASA score	2.4 ± 0.5	2.6 ± 0.4	.75
SVS cardiac score	0.91 ± 0.89	0.81 ± 0.94	.93
SVS pulmonary score	0.57 ± 0.85	0.48 ± 0.82	.94
SVS renal score	0.31 ± 0.64	0.28 ± 0.57	.97
SVS sum score	0.85 ± 0.44	0.82 ± 0.46	.96

ASA, American Society of Anesthesiologists; *BMI,* body mass index; *CABG/PTCA,* coronary artery bypass graft/percutaneous transluminal coronary angioplasty; *COPD,* chronic obstructive pulmonary disease; *Cr,* creatinine; *CRI,* chronic renal insufficiency; *EVAR,* endovascular aneurysm repair; *SVS,* Society for Vascular Surgery.
[a]Data presented as the mean ± standard deviation or number (%).
[b]Includes current and former smokers.
[c]Statistically significant.

Table II. Preoperative aneurysm sac characteristics and anatomical spectrum for the 162 patients with infrarenal aortic abdominal aneurysms who underwent standard EVAR (group A) and EVAR with aneurysm sac embolization (group B)

	Group A (n = 83)[a]	*Group B (n = 79)*[a]	P *value*
Aneurysm sac characteristics			
Volume, cm^3	144 ± 97	128 ± 68	.89
Diameter, cm	5.7 ± 1.1	5.8 ± 0.9	.94
Anatomical spectrum			
Patent inferior mesenteric artery	58 (70)	66 (83)	.04[b]
Patent lumbar artery pairs			
1 pair	21 (25)	18 (23)	.71
2 pairs	40 (48)	37 (47)	.87
≥3 pairs	22 (26)	24 (30)	.6
Accessory renal arteries[c]	2 (2)	3 (4)	.67
Percentage of thrombus volume			
0%-25%	20 (24)	19 (24)	.63
26%-50%	46 (55)	48 (60)	1.0
51%-75%	17 (20)	12 (15)	.52
Other concomitant aneurysms			
Associated monolateral iliac aneurysm	6 (7)	5 (6)	1.0
Associated bilateral iliac aneurysm	1 (1)	—	—
Iliac aneurysm diameter, mm	2.46 ± 0.2	2.43 ± 0.3	.93

EVAR, Endovascular aneurysm repair.
[a]Data presented as the mean ± standard deviation or number (%).
[b]Statistically significant.
[c]Accessory renals arising from aneurysm sac or required to be covered by the endograft.

identified in distribution of thrombus or patency of lumbar or accessory renal arteries (Table II).

The mean duration of the embolization procedure was 14 ± 3 minutes in group B. This time did not modify the overall operative time between the two groups (185 ± 52 minutes vs 179 ± 49 minutes; $P = .92$). Intraoperatively, a significantly increased number of patients underwent general anesthesia in group B than in group A (75% vs 54%; $P = .008$), whereas there were no differences in requirements for transfusion of blood products (446 ± 120 vs 483 ± 133; $P = .83$). A smaller number of Cook Zenith (Cook Medical) ($P = .02$) and larger number of Jotec E-vita (Jotec, Hechingen, Germany) ($P = .005$) abdominal endografts were implanted in group B than in group A, whereas no differences were reported between the groups in the number of additional intraoperative endovascular procedures (Table III). No statistically significant differences were found in the distribution of frequency of EII among the different types of grafts during follow-up at 3, 6, 12, and 18 months. In particular, the frequency of EII at the first CT angiogram follow-up ranged from 20% to 26% for the four most frequently used endografts in group A (Cook, 22%, Gore, 26%, Medtronic, 20%, Jotec, 20%) and from 8% to 14% in group B (Cook, 8%, Gore, 11%, Medtronic, 12%, Jotec, 14%).

Interestingly, even though the number of EIIs detected at the final intraoperative angiogram was lower in group B (15% vs 22%), the difference was not statistically significant ($P = .31$).

No differences were reported between the two groups in terms of major medical or surgical complications within 30 days (Table IV). Technical success was 100% for both groups, and no aneurysm ruptures or deaths were reported in this series; in particular, all embo-EVAR procedures in group B were successful. The first CT angiogram obtained during follow-up (within 30 days and 3 months) showed a significantly higher rate of EIIs in group A than in group B (24% vs 10%; $P = .02$). The descriptive analysis of freedom from EII illustrated in Fig 3 shows that group B had significantly higher success rates at 3 and 6 months ($P = .02$ and .03, respectively), but this was not borne out during midterm follow-up (at 18 months; $P = .32$).

During midterm follow-up (18 months), spontaneous EII resolution occurred in 65% of patients in group A and 79% in group B ($P = 1.0$), whereas sac volume

Table III. General operative and procedural information by standard EVAR (group A) and EVAR with aneurysm sac embolization (group B)

	Group A (n = 83)[a]	*Group B (n = 79)*[a]	P *value*
Operative data			
General anesthesia	45 (54)	59 (75)	.008[b]
Transfusion, mL	446 ± 120	483 ± 133	.83
Operative time, minutes	185 ± 52	179 ± 49	.92
Radiation exposure, minutes	26 ± 5.2	25 ± 7.3	.85
Length of stay, days			
Intensive care unit	0.8 ± 1.9	0.9 ± 2.1	.97
Hospital	3.6 ± 0.7	3.1 ± 0.9	.65
Procedural data			
Type of endograft			
Cook, Zenith	49 (59)	34 (43)	.02[b]
Gore, Excluder	19 (23)	20 (25)	.85
Medtronic, Endurant	10 (12)	9 (11)	1.0
Jotec, E-vita Abdominal	5 (6)	17 (21)	.005[b]
Vascutek, Anaconda	1 (1)	—	—
Embolization			
Fibrin glue, mL	—	5	—
Coils	—	3	—
Additional endovascular procedures			
Proximal cuff	7 (8)	3 (4)	.16
Distal iliac extension	3 (4)	1 (1)	.62
Type II endoleaks at final angiogram	18 (22)	12 (15)	.31

EVAR, Endovascular aneurysm repair.
[a]Data are presented as the mean ± standard deviation or number (%).
[b]Statistically significant.

Table IV. Early outcomes (≤30 days after surgery) in the 162 patients with infrarenal abdominal aortic aneurysms treated with standard EVAR (group A) and EVAR with aneurysm sac embolization (group B)

Outcomes (≤30 days)	*Group A (n = 83)*[a]	*Group B (n = 79)*[a]	P *value*
Medical outcomes			
Major cardiac[b]	1 (1)	0 (—)	.48
Respiratory failure[c]	1 (1)	1 (1)	.49
Dialysis	0 (—)	0 (—)	—
Death	0 (—)	0 (—)	—
Surgical outcomes			
Technical success	83 (100)	79 (100)	—
Primary clinical success	78 (94)	75 (95)	1.0
Rupture	0 (—)	0 (—)	—
Conversion	0 (—)	0 (—)	—
Related death	0 (—)	0 (—)	—
Early additional reintervention[d]	5 (6)	4 (5)	1.0
Endoleaks			
Type IA	1 (1)	0 (—)	.48
Type IB	2 (2)	2 (2)	.61
Type II	0 (—)	0 (—)	—
Arterial femoral access[e]	1 (1)	2 (2)	1.0
Limb ischemia/thrombosis	1 (1)	0 (—)	.48
Distal embolization	0 (—)	0 (—)	—

EVAR, Endovascular aneurysm repair.
[a]Data expressed as the number (%).
[b]Intraoperative or perioperative major cardiologic event that required intervention (cardiac massage, coronary artery bypass grafting, percutaneous transluminal angioplasty, pacemaker implantation).
[c]Pulmonary embolism or severe respiratory distress.
[d]Requiring surgical or endovascular additional reintervention within 30 days.
[e]Intended as bleeding or arterial wall dissection in the site of puncture requiring surgical revision.

increased in 25% of group A vs 10% of group B, respectively ($P = .63$). The overall difference in mean sac volume shrinkage was similar for the two groups (27 ± 12 cm^3 vs 25 ± 12 cm^3; $P = .19$).

In the Kaplan-Meier estimates at 18 months for freedom from reintervention (Fig 4), group A had a significantly lower rate than group B (93% vs 99%; $P = .03$). In particular, during this period, five patients in group A underwent six reinterventions: two patients underwent coil embolization for patent inferior mesenteric artery, with a repeated procedure in one of the two after 6 months; and three patients underwent coil embolization of patent lumbar arteries. In group B, only one patient (1%) underwent coil embolization of a couple of patent sacral arteries 10 months after EVAR. In both groups, the indication for reintervention was in all cases the presence of an EII with aneurysm sac growth >5 mm.

In our institution, the cost for a single patient embolization during EVAR with this technique was calculated to be ≈607á ($800), whereas the institutional reimbursement expenses for a secondary reintervention for embolization with coils of an EII after EVAR is ≈9.000á ($11,800). Considering that during follow-up, six reinterventions were performed in group A and sac embolization in all 79 patients and reintervention in only one patient in group B, the total costs were ≈54.000á ($71,000) for group A and 57.000á ($75,000) for group B.

We carefully explored multivariate modeling for EII, which showed that the only reliable independent predictor of EII was preoperative aneurysm sac volume >125 cm^3 (odds ratio [OR], 4.0; 95% confidence interval [CI], 1.5-10.5; $P = .005$); there was only a slight trend toward preoperative aneurysm maximum diameter >5.7 cm being a predictive factor (OR, 2.4; 95% CI, 0.9-6.0; $P = .054$). Interestingly, even though a significantly larger number of IMAs were patent preoperatively in group B than in group A, this was not a positive predictor of EII ($P = .65$).

Presence of thrombus as a percentage of volume and presence of thrombus as the number of patent branches, both separately and combined, did not appear to be a reliable predictor (Table V).

DISCUSSION

The approach to EII changed dramatically over time; 10 years ago, EIIs were treated much more frequently, whereas recently, clinical evidence has confirmed that many EIIs are innocuous and only those causing persistent sac enlargement deserve aggressive treatment. The literature reports a secondary intervention success rate of

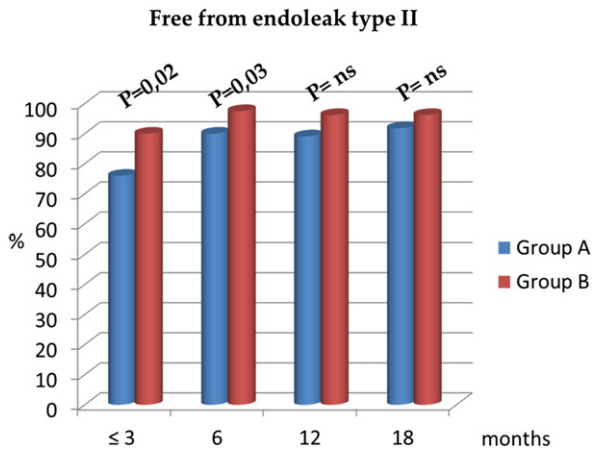

Fig 3. Descriptive analysis of freedom from type II endoleaks (EIIs) during early and midterm follow-up in groups A and B.

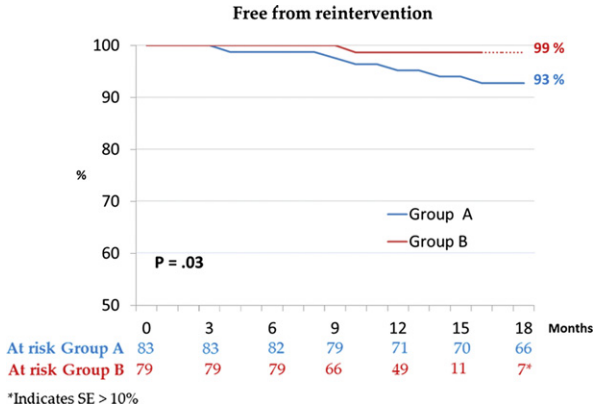

Fig 4. Kaplan-Meier curve for freedom from type II endoleak (EII)-related reintervention during early and midterm follow-up in groups A and B. *SE,* Standard error.

43%,[11] and in some cases, the only definitive solution may be surgical conversion.

Recently, on the basis of different experience, there has been a trend toward preventing EIIs instead of treating their complications after they develop. Brenes et al[12] reported laparoscopic IMA ligation before EVAR; Muthu et al[13] have described routine intraoperative selective IMA embolization and thrombin injection into the aneurysm sac just before EVAR.

Zanchetta et al[14] showed that the injection of fibrin glue into the aneurysm sac during EVAR significantly reduces EIIs compared with standard EVAR. This group reported further experience using variable doses of fibrin glue in association with coil embolization,[7] with a significant reduction in EIIs compared with standard EVAR (hazard ratio, 0.13; 95% CI, 0.05-0.36; $P < .0001$). A subsequent study by Pilon et al,[8] using both fibrin glue and coils, reported a comprehensive reduction in health care costs in patients who underwent EVAR plus

Table V. Final model of multiple logistic regression for preoperative aneurysm sac dimensional characteristics and anatomical spectrum in relation to EIIs

	OR	*Inferior*[a]	*Superior*[a]	P *value*
Group B				
Patent inferior mesenteric artery	.7	.2	2.5	.657
Patent lumbar artery pairs	—	—	—	.809
Patent accessory renals	2.1	.3	13.1	.409
Percentage of thrombus volume	—	—	—	.421
Group A				
Patent inferior mesenteric artery	.6	.2	2.1	.472
Patent lumbar artery pairs	—	—	—	.811
Patent accessory renal arteries	2.9	.5	18.7	.249
Percentage of thrombus volume	—	—	—	.396
Groups A and B	3.3	1.3	8.4	.012[b]
Maximum sac diameter >5.7 cm	2.4	.9	6.0	.054
Sac volume >125 cm^3	4.0	1.5	10.5	.005[b]

CI, Confidence interval; *EIIs,* type II endoleaks; *OR,* odds ratio.
[a]95% CI for OR.
[b]Statistically significant.

embolization compared with those who underwent standard EVAR. In our opinion, the combination of fibrin glue and coils to facilitate aneurysm sac thrombosis and prevent EII formation represents a valid method. We decided to change our practice based on the fact that this technique does not require selective cannulation and embolization of side branches but only sac filling. These changes do not interfere significantly with the standard EVAR procedure in terms of operative time, dose of contrast used, and extremely higher costs related to adjunctive microcather and coils to be used.

Currently, however, there is no reliable method for predicting the exact amount of material to be injected into the sac to effectively prevent EII. In previous reports, the amount of material injected was usually ≥5 mL of fibrin glue and ≥1 coils. When the final angiographic control revealed the persistence of EII, the dose of material was increased. The use of a "standard" dose of material indicates, in our experience, that the procedure was safe with no differences in peri- and postoperative morbidity and mortality between the two groups analyzed.

During follow-up, we had a significant reduction of EIIs within only 3 months and at 6 months between the two groups ($P = .02$ and .03 respectively), whereas after this period, the number of EIIs was still lower in group B but did not reach statistical significance. On the other hand, freedom from reintervention was significantly higher in group B as compared with group A in the Kaplan-Meier estimates at 18 months ($P = .03$).

Sac volume analysis in patients with EIIs revealed that the number of patients with increased volumes during

follow-up was higher, although not significantly ($P = .63$), in group A than in group B (25% vs 10%) even if not significant. Thus, we can assume that even in the presence of similar percentages of EIIs, the patients who underwent embo-EVAR were more protected from the insidious evolution of EII with sac expansion or endoleak persistence that usually requires additional intervention. In addition, after EVAR, EII embolization may not be effective, thus secondary additional procedures may be required, as occurred in one case in group A (20%). This finding is in accordance with recent results published by Sarac et al,[15] who reported a need for secondary embolization in 20% of cases with a 5-year freedom from secondary embolization of 76% (95% CI, 66%-86%).

We tried to determine if any of the known preoperative CT angiogram morphological predictors[16-18] of endoleak could be useful in predicting the efficacy of this technique. In this regard, we believe that aneurysm dimensions are strictly related to the amount of material needed. The dimensions of aneurysm sacs have traditionally been evaluated on the basis of maximum aneurysm diameter. Recently, there have been several reports on the use of volumetric analysis to better determine the dimensions of aneurysm sacs.[19] Cani[20] showed that volume calculation, which differs from maximum diameter calculation, is a precise method for evaluating modifications of the aneurysm sac independently from the operator. Furthermore, Fillinger,[21] in 2006, reported for the Pivotal Trial that three-dimensional volume criteria detect aneurysm sac enlargement during EVAR follow-up more frequently and sooner than do standard diameter criteria.

Use of a maximum aneurysm diameter >5.7. cm to predict EIIs after embo-EVAR did not attain statistical significance ($P = .054$), although this may represent a type II statistical error. Conversely, an aneurysm sac volume >125 cm^3 turned out to be a robust independent predictor of EIIs, with an OR of 4.0 ($P = .005$), indicating that embo-EVAR is effective only for aneurysms with preoperative volumes <125 cm^3. This finding prompted us to consider volume as the principal factor to be investigated preoperatively to optimize the dose of material injected and be effective in EII prevention.

Our study has some limitations that are worthy of mention. This was a retrospective, nonrandomized study in a small cohort of patients. Longer follow-up is ideal and may produce data that could alter our current conclusion. Unfortunately, this technique was recently developed with no standardized indication yet and only a little experience reported in the literature. Nevertheless, we selected all patients for a careful and complete follow-up with adequate imaging, allowing robust assessment of early and midterm outcomes. The homogeneity of the two groups and the injection of a standard dose of material for embolization could guarantee reliable findings.

Results of this study, even in the presence of a significant reduction in EII-related reintervention, still reveal a moderate reduction in EII frequency, especially at the midterm follow-up. A step forward in improving the efficacy of this technique would be to limit its use only to those patients at high preoperative risk of endoleaks and to adjust the dose of material injected on the basis of preoperative aneurysm volume.

CONCLUSIONS

To our knowledge, no other published study has compared aneurysm sac embolization during EVAR using a standard dose of fibrin glue and coils with traditional EVAR. Although further confirmatory studies are needed, this technique may be a safe and valid approach to preventing EIIs and their complications during short- and midterm follow-up. More aggressive intraoperative embolization should be considered for patients with a preoperative aneurysm sac volume >125 cm^3.

AUTHOR CONTRIBUTIONS

Conception and design: MP, PF
Analysis and interpretation: MP, FN
Data collection: PS
Writing the article: MP
Critical revision of the article: MP, PF, JR, FG, MA
Final approval of the article: MP, PF, PS, SB, FN, FG, JR, MA
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MA and FG contributed equally to this article.

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